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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,807	05/25/2001	John J. Carrino	265/018	4619

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/14/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,807

Applicant(s)

CARRINO ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60, 78-119, 133, 136-141, 160-168, 176-197 and 204-210 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60, 78-119, 133, 136-141, 160-168, 176-197 and 204-210 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment C

Applicants' amendment, filed 28 October 2002, has been acknowledged. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 60, 78-119, 133, 136-141, 160-168, 176-197 and 204-210 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60, 78-119, 133, 136-141, 160-168, 176-197 and 204-210 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60, 78, 100, 106, 111, 136, 160, 176 and 204 are vague and indefinite due to the lack of clarity in the abbreviated term "SDA" as seen in line 12 of claim 60. It is unclear as to that which SDA is to be representative of since nowhere in the claim is the written out version pointed to with its abbreviation following in parentheses. As such, claims 79-109, 101-105, 107-110, 112-119, 137-141, 161-168, 177-197 and 205-210 are also indefinite due to their dependency from claims 60, 78, 100, 106, 111, 136, 160, 176 and 204.

Claims 60, 106 and 111 are vague and indefinite due to the order of steps in methodology. The claims indicate (i.e. claim 60, line 15) that steps (a)-(c) occur "at the same time" however it appears that the events of these steps must occur consecutively, or at least in relation to each other. For example, in order for the strand displacement amplification reaction to occur, the upstream and downstream probes must be already in contact with the target nucleic acid sequence, otherwise the reaction would not appear to occur if the probes were not in place. In addition, claim 111 further demonstrates a sequential order of events in that the method includes probes that are "initially incapable of being ligated together" (line 16) followed by a

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step that then renders the probes "capable" (line 17); all "prior to ligating the probes together in step (b)" (lines 18-19). As such, claims 107-110 and 112-119 are also indefinite due to their dependency from claims 60, 106 and 111.

Claims 60, 78, 100, 106, 111, 136, 160, 176 and 204 are vague and indefinite due to the lack of clarity in the phrase "primer comprising a restriction endonuclease sequence upstream of a sequence specific for the ligated target probe template" (claim 60, lines 12-14). It is unclear as to which part of the ligated probe template is the specified sequence being referenced to be "upstream of": the target nucleic acid sequence or the upstream or downstream probe sequences. As such, claims 79-109, 101-105, 107-110, 112-119, 137-141, 161-168, 177-197 and 205-210 are also indefinite due to their dependency from claims 60, 78, 100, 106, 111, 136, 160, 176 and 204.

Claims 78, 100, 136 and 176 are vague and indefinite due to the lack of clarity in the first and second SDA primers utilized. It is unclear as to whether the primers are the same or different thus unclear as to where the primers are targeted to in the ligated target probe template. As such claims 79-109, 137-141 and 177-197 are also indefinite due to their dependency from claims 78, 100, 136 and 176.

The term "effective" in claims 78 and 176 is a relative term that renders the claim indefinite. The term "effective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such claims 79-99 and 177-197 are also indefinite due to their dependency from claims 78 and 176.

Claims 86 and 184 are vague and indefinite due to the lack of clarity of the term "competitor" line 2. It is unclear as to the metes and bounds of the parameters that define a competitor; a nucleic acid sequence or a peptide sequence for example, or a competitor to the primers themselves to bind to the ligated target probe template or to bind to the primers. As such claims 87-99 and 185-197 are also indefinite due to their dependency from claims 86 and 184.

Claim 106 and 204 are vague and indefinite due to the lack of clarity in step of the allele specific probes contacting "a portion of the target nucleic acid sequence which is determinative of the allele" (claim 106, lines 20-21). It is unclear as the metes and bounds of the parameters that define a "portion" that is of the target nucleic acid sequence and fulfills the requirements that

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are determinative of the allele sequence. As such claims 107-110 and 205-210 are also indefinite due to their dependency from claims 106 and 204.

Claims 111 and 160 are vague and indefinite due to the lack of clarity in the order of the steps of methodology. It is unclear at which point the probes are "render[ed] capable of being ligated together"; prior to contact with the target nucleic acid sequence (a), or after (a) but still prior to (b). As such claims 112-119 and 161-167 are also indefinite due to their dependency from claims 11 and 160.

Claim 136 recites the limitation "the capture site" in line 16. There is insufficient antecedent basis for this limitation in the claim. As such claims 137-141 are also indefinite due to their dependency from claim 136.

Claim 177 recites the limitation "the set" in line 3. There is insufficient antecedent basis for this limitation in the claim. There is antecedent basis for "the set of primers" in claim 176, line 16. As such claims 178-183 are also indefinite due to their dependency from claim 177.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M. to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 13, 2003

Monika B. Sheinberg
Art Unit 1634

**JEHANNE SOUAYA
PATENT EXAMINER**

Jehanne Souaya
1/13/03